GensiaSicor™
PHARMACEUTICALS
A sicor Company

May 5, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061, HFA-305
5630 Fishers Lane
Rockville, Maryland 20852

5341 '00 MAY -8 A11:19

RE: ANDA Suitability Petition
Propofol Injectable Emulsion 1%, 10 mg/mL
Formulation Containing 0.025% Sodium Metabisulfite

ANDA Suitability Petition

The undersigned submits this Suitability Petition (the "Petition") under the provisions of the Federal Food, Drug and Cosmetic Act, Section 505(j)(2)(c) and 21 CFR §314.93 to request the Commissioner of Food and Drugs to allow submission of a supplement to an abbreviated new drug application (ANDA) for Propofol Injectable Emulsion 1% with 0.025% Sodium Metabisulfite in a strength of 100 mg/10 mL, single use vial.

A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs permits a change in the total drug content (strength) to allow for submission of a supplement to an abbreviated new drug application (ANDA) for Propofol Injectable Emulsion 1% with 0.025% Sodium Metabisulfite in a strength of 100 mg/10 mL, single use vial. The basis of the Petition is the reference listed drug product, Diprivan®, marketed by the innovator, AstraZeneca (then Zeneca), which is available in four (4) presentations: single use ampoule containing 200 mg/20 mL, single use vials containing 500 mg/50 mL and 1000 mg/100 mL, and a single use prefilled syringe containing 500 mg/50 mL. AstraZeneca received approval of NDA 19-627 on June 11, 1996, for Diprivan® (propofol injectable emulsion 1%).

B. Statement of Grounds

The subject of the Petition for Propofol Injectable Emulsion 1% with 0.025% Sodium Metabisulfite is to permit a change in the total drug content (strength). The reference listed drug product, Diprivan®, marketed by the innovator, AstraZeneca, received approval of NDA 19-627 on June 11, 1996, and is available in the four (4) aforementioned sizes.

Gensia Sicor's proposed drug product will be packaged in a single use vial at the same concentration, 10 mg/mL, as the reference listed drug product, but in a different strength of 100 mg/10 mL.

Product	Dosage Form	Route of Administration	Drug Concentration	Strength
INNOVATOR'S Diprivan®	Sterile Emulsion	Intravenous	10 mg/mL	200 mg/20 mL (A)[1] 500 mg/50 mL (V)[2] 1000 mg/100 mL (V) 500 mg/50 mL (S)[3]
(Proposed) GENSIA SICOR'S Propofol Injectable Emulsion 1%	Sterile Emulsion	Intravenous	10 mg/mL	100 mg/10 mL (V)

[1] Single Use Ampoule
[2] Single Use Vial
[3] Prefilled Syringe

The smaller vial size will provide the practitioner with a wider range of dosing flexibility. Because the product is unpreserved, a smaller vial size is safer in that it may reduce the temptation for dosing multiple patients from a single container thereby reducing opportunities for microbial contamination. Additionally, the proposed smaller vial size more closely supports induction and monitored anesthesia care (MAC) sedation dosages based on a typical range of adult and pediatric patient body weights. The proposed drug will provide a reduction in hazardous waste disposal and cost for the course of therapy. The subject drug is intended for use only as described in the **Indications** and **Dosage and Administration** sections of the draft package insert appended in **Attachment 1**. To support this Petition, a Medical Rationale for the proposed product strength is provided in **Attachment 2**.

Appended in **Attachment 3** is the package insert for Diprivan® (propofol injectable emulsion 1%), AstraZeneca. The labeling for the proposed drug is essentially identical to that of AstraZeneca's Diprivan® (propofol injectable emulsion 1%), but differs only with respect to the description of the product, product name, preservative, the how-supplied statement, and the specific manufacturer's information.

C. Environmental Impact

In accord with 21 CFR §25.24(c)(1), an Environmental Impact Analysis Statement is not required if there is a determination that Propofol Injectable Emulsion 1% with 0.025% Sodium Metabisulfite is suitable for ANDA status.

D. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

We trust you will find the information in the Petition to be satisfactory for your review and approval. Should you have any questions or require further clarification, please contact me at (949) 457-2808.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

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